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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/663,449      | 09/16/2003  | Timothy J. Fischer   | 00824Div.JAR        | 2189             |

7590

08/02/2005

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| EXAMINER |
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GITOMER, RALPH J

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| ART UNIT | PAPER NUMBER |
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1655

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/663,449

Applicant(s)

FISCHER ET AL.

Examiner

Ralph Gitomer

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 60,63,65-69,74,78,79,87,88,91-94,188,206,225,226 and 228 is/are pending in the application.
- 4a) Of the above claim(s) 225,226 and 228 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60,63,65-69,74,78,79,87,88,91-94,188,206,225,226 and 228 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Applicant's election without traverse of Group I in the reply filed on 6/23/05 is acknowledged. In view of the preliminary amendment received 9/16/03, the following claims are considered here: 60, 63, 65, 66-69, 74, 78-79, 87, 88, 91-94, 188, 206. Claims 225, 226, 228 are withdrawn from consideration as non-elected without traverse.

The specification refers to a number of references such as Givens but does not include complete citations. A complete bibliography is required. No IDS is found in this file.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 188 and 206 are drawn to a method which is not found in the specification as originally filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 60, 63, 65, 66-69, 74, 78-79, 87, 88, 91-94, 188, 206 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

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There are many instances of lack of antecedent basis in the claims. In claim 60 line 1, "the coagulation system" lacks antecedent basis. In claim 63 line 2, what the protein C is added to is not set forth. In claim 65 line 3, what the vesicles are included in is not set forth. In claim 74 line 1, "the rate" lacks antecedent basis. In claim 78(b) "triggering" is queried. In claim 87 "said fibrin polymerization profile" lacks antecedent basis. In claim 92 "said at least one parameter" lacks antecedent basis. In claim 188(i) "the second patient sample" lacks antecedent basis. In claim 188(j) "the effectiveness" and "the pharmaceutical therapy" lack antecedent basis. In claim 206(i) "the degree" lacks antecedent basis. In claim 206(j) "the efficacy" lacks antecedent basis.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because of the restriction. Correction is required. See MPEP § 608.01(b).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Tejidor (6,645,768) teaches a reagent for assessing a coagulation system.

Braun (6,321,164) teaches time dependent profiles of coagulation.

Fischer (6,743,596) is the parent patent.

Toh (WO 00/46603) teaches tem dependent coagulation profiles.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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